

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SOHN *et al.*

Appl. No.: 10/586,045

Filed: June 12, 2007

For: **Rapid Screening Method of
Translational Fusion Partners for
Producing Recombinant Proteins and
Translational Fusion Partners
Screened Therefrom**

Confirmation No.: 2495

Art Unit: 1639

Examiner: STEELE, Amber D.

Atty. Docket: 2472.0010000/EKS/BNC

Reply to Restriction and Election of Species Requirement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated August 7, 2009, requesting an election of one invention to which the claims must be restricted in the above-captioned patent application, Applicants hereby provisionally elect **Group I**, represented by claims 18-38. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made **with** traverse.

Applicants respectfully submit that restriction to one of six groups is not proper. The Examiner states that "[t]he inventions listed as Groups I-VI do not relate to a single inventive concept . . . because, under PCT Rule 13.2, they lack the same or corresponding technical features for the following reasons: the common technical feature is a TFP and the polynucleotide that encodes a TFP which is known in the prior art." (Office Action at page 3, paragraph 3). Further, the Examiner alleges that Boquet *et al.* teaches polynucleotides encoding fusion proteins comprising a protein fused to a reporter and Mascarenhas *et al.* teaches

polynucleotides encoding fusion proteins comprising a protein fused to a portion of another protein to allow for secretion of the fusion protein (Office Action at page 3, paragraph 3). Applicants respectfully traverse these contentions.

Even assuming, *arguendo*, that Groups I-VI do not relate to a single inventive concept, Applicants submit that to search and examine the subject matter of Groups I-VI together would not be a serious burden on the Examiner. One of the criteria for a proper requirement for restriction is that: "There would be a serious burden on the examiner if restriction is not required . . ." *See* M.P.E.P. § 803. Thus, the Patent Office encourages the search and examination of an entire application on the merits, where such search and examination can be made *without* serious burden. Applicants respectfully assert that the search of restriction Groups **I-VI** does not impose a serious burden upon the Examiner, as a search concerning the patentability of Group I will clearly uncover publications of interest to the other groups.

In particular, Group I relates to methods of identifying a TFP for secretion of a target protein, the method comprising:

- a) preparing an automatic screening vector comprising a polynucleotide encoding said target protein linked in frame to a polynucleotide encoding a reporter protein;
- b) linking a plurality of polynucleotide fragments to said automatic screening vector to create a library;
- c) transforming said library into cells having no activity of said reporter protein;
- d) culturing said cells; and

e) identifying a TFP by detecting reporter protein activity secreted from one or more of said cells.

Group II, claims 39-58, is drawn to a method of producing a TFP library, and Group III, claim 59, is drawn to a TFP library produced by the methods of group II. Claim 18(a)-(d) of Group I includes similar aspects as claim 39(a)-(d) of Group II. In particular claim 18(b) and claim 39(b), relate to linking a plurality of polynucleotide fragments...to create a library. In addition, the claim of Group III depends directly from a claim of Group II. Thus, searching Group I will clearly uncover publications of interest to Groups II and III.

Group IV, claims 60-61, is drawn to a TFP identified by the method of claim 18 (Group I), and Group V, claims 62-68, is drawn to a polynucleotide encoding a TFP of claim 60 (Group IV). Group I relates to a method of identifying a TFP, and Groups IV and V are related to a TFP or polynucleotide encoding the same, which is identified by the methods in Group I. In addition, the claims of Groups IV and V depend directly or indirectly from a claim of Group I. Thus, searching Group I will clearly uncover publications of interest to Groups IV and V.

Furthermore, Group VI, claims 69-71, is drawn to a method of producing a target protein. The method of claim 69 includes preparing an expression vector comprising a polynucleotide encoding said target protein fused to a polynucleotide encoding a TFP of claim 60 (Group IV). Similarly, within Group I, claim 18(a) relates to preparing an automatic screening vector comprising a polynucleotide encoding said target protein linked in frame to a polynucleotide encoding a reporter protein. In addition, the claims of Group VI depend directly or indirectly from a claim of Group IV. Thus, searching Groups I and IV will clearly uncover publications of interest to Group VI.

Thus, Applicants submit that in the present case, restriction to one of six groups, as required by the Examiner, is improper and presents an undue burden to Applicants to prosecute six patent applications. Therefore, it is respectfully requested that Groups **I-VI** (claims 18-71) be searched and examined together in the subject application. Alternatively, it is respectfully requested that at least Groups **I, II, and III** (claims 18-59) be searched and examined together.

Species Election Requirement

The Examiner further requests an election of a single species within Group I for (a), (b), (c), (d) and (e) as specified at page 3, paragraph 4 of the Office Action. Applicants hereby provisionally elect following species:

- (a) human interleukin-2 (at least claims 18-38 read on such species),
- (b) yeast genomic DNA (at least claims 18-23 and 25-38 read on such species),
- (c) *Saccharomyces cerevisiae* (at least claims 18-38 read on such species),
- (d) invertase (at least claims 18-38 read on such species), and
- (e) automatic screening vector comprising a GAL10 promoter (at least claims 18-38 read on such species).

This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This species election is made **with** traverse.

The Examiner asserts that these species lack unity of invention because they are not so linked as to form a single inventive concept under PCT Rule 13.1. In particular, the Examiner states that "the species lack the same or corresponding special technical features for the following reasons: the species are structurally and functionally different." Office Action at page 4, paragraph 9. Applicants respectfully traverse these contentions.

Even assuming, *arguendo*, that (a)-(e) each include species that lack the same or corresponding special technical features, Applicants submit that to search and examine the subject matter of the species together would not be a serious burden on the Examiner. For example, since the allegedly different species of (a) relate to methods involving a target protein for secretion, *e.g.*, human interleukin-1, searching for similar methods that include target proteins would naturally lead to publications which disclose other target proteins for secretion such as those in claims 20-22. Accordingly, it would not be an undue burden for the Examiner to search and/or examine the species of (a) together.

Since the allegedly different species of (b) include a plurality of nucleotide fragments used in the method described in claim 18 for identifying a TFP for secretion of a target protein, searching similar methods using animal, plant, or microorganism DNA (source) that is genomic or cDNA (type), *e.g.*, yeast genomic DNA, would naturally lead to publications which disclose methods using other DNA source and type such as those in claims 23-27. Accordingly, it would not be an undue burden for the Examiner to search and/or examine the species of (b) together.

Since the allegedly different species of (c) include eucaryotic or bacterial cells used in the method of claim 18 for identifying a TFP, searching similar methods using eucaryotic or bacterial cells, *e.g.*, *Saccharomyces*, would naturally lead to publications which disclose

methods using other cells such as those in claims 28, 29 and 38. Accordingly, it would not be an undue burden for the Examiner to search the species of (c) together.

Since the allegedly different species of (d) include reporter proteins used in the method of claim 18 for identifying a TFP, searching similar methods using reporter proteins, *e.g.*, invertase, would naturally lead to publications which disclose methods using other reporter proteins such as those in claims 30-32 and 38. Accordingly, it would not be an undue burden for the Examiner to search the species of (d) together.

Since the allegedly different species of (e) include automatic screening vectors used in the method of claim 18 for identifying a TFP, searching for similar methods using automatic screening vectors, *e.g.*, automatic screening vector comprising a GAL10 promoter, would naturally lead to publications which disclose other automatic screening vectors such as those in claims 33-37. Accordingly, it would not be an undue burden for the Examiner to search the species of (e) together.

Applicants respectfully submit that the Examiner has not made a proper showing of the burden of searching the allegedly distinct species. Hence, Applicants respectfully request that the election of species requirement be withdrawn, and that the generic terms be examined. *See* M.P.E.P. § 803. In accordance with 37 C.F.R. § 1.141(a), Applicants also reserve the right to claim additional species, and/or to have additional species searched and/or examined, in the event that a generic claim is found to be allowable.

Reconsideration of the Restriction and Election of Species Requirements, and consideration and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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